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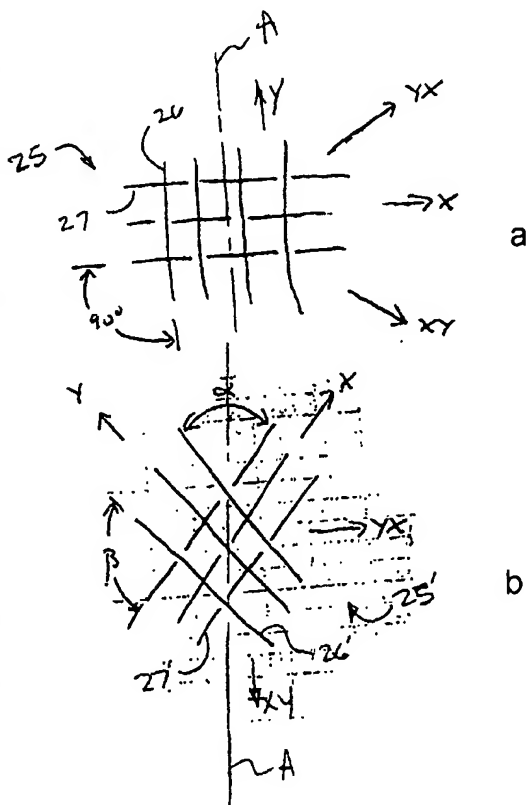
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(54) Title: WOVEN ORTHOPEDIC IMPLANTS



(57) Abstract: The present invention relates to orthopedic implants made from a mesh material. The mesh material can be treated in order to promote bone growth, to provide antibiotics, or to provide other beneficial treatment. Specific applications for the implants include, for example, a prosthetic ligament, a tension band, an interbody device, or a fixation device that extends across one or more joints or fractures.

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WOVEN ORTHOPEDIC IMPLANTS

The present application claims the benefit of United States Provisional
Application Serial No. 06/272,246, filed on February 28, 2001 and United States
Application filed on February 25, 2002, Attorney Docket Number 4002-2949/PC462.00,
which are hereby incorporated by reference in their entirety.

FIELD OF THE INVENTION:

The present invention relates to orthopedic implants, and more
particularly, to orthopedic implants made from metal mesh material.

BACKGROUND OF THE INVENTION

In order to stabilize a bone or bony segment, such as the spinal column or a
fractured bone, it is known to secure a rigid metal plate, rod, or other rigid support to the
bone portions comprising the bone segment. Such rigid supports are useful, for example,
in stabilizing and immobilizing a fracture of the bone since the support can be secured to
the bone portions on each side of the fracture.

With respect to the spinal column, various techniques require access to an
intervertebral disc space. Examples of such techniques include the repair of a herniated
disc or the insertion of one or more interbody fusion devices, interbody spacers, or
artificial discs. In order to access the disc space, one or more spinal ligaments and bony
tissue may have to be severed or at least partially resected to allow insertion of surgical
instruments and implants into the disc space. Posterior or anterior rigid metal supports
can be used to stabilize the spinal column after these techniques are completed.
Furthermore, devices inserted in the disc space can be made from rigid, inert metal
material, bone material, or polymeric material.

It has been stated by some writers that the use of rigid metal plates to immobilize
bones and bony portions can have certain drawbacks since such a plate will be in close
contact with the vasculature and tissue along the bone. For example, it has been stated

that the potential for screw back out and plate loosening creates a risk for erosion of the vasculature and the surrounding tissue. It has also been stated that rigid metal plates could bend in an undesired manner or break due to compressive loading and fatigue of the metal. A fracture or undesired bend in the plate could erode the tissue and vasculature surrounding the plate. Metal plates could also cause stress shielding.

In situations where spinal fusion is desired, it is known to place rigid metal supports in the disc space. Bone growth material can be placed in these supports. However, in the case of metal supports, openings must be formed through the walls of the support to accommodate fusion. In order to maintain the ability of the support to resist the in-vivo loads, these holes must be limited in number and in size so that the implant retains its structural integrity, providing relatively large regions on the implant which have no bone ingrowth.

Improved orthopedic implants that avoid at least some of the problems associated with rigid supports are therefore needed. The implants should be resistant to fatigue, stress shielding and the loads that are typically applied to the bone or bony segment. What is further needed are improved orthopedic implants to repair or replace resected ligaments or bony tissue, while the implant promotes bone ingrowth, fusion and/or healing. Also needed are improved orthopedic implants that have a profile that is as low as possible to avoid the potential complications associated with the vasculature and other tissue in this anatomic region. In addition, it is desirable to have orthopedic implants that avoid the complications with rigid supports. The present invention is directed toward meeting these needs, among others.

SUMMARY OF THE INVENTION

The present invention relates to orthopedic implants made at least partially from metal mesh material to form an orthopedic implant. In a preferred form, the metal mesh material includes metal wire of suitable tensile strength and which is not subject to substantial creep deformation or in vitro degradation. In a further preferred form, the mesh material can be treated in order to promote bone growth, to deliver pharmaceutical agents, such as antibiotics, anti-inflammatories or other beneficial treatments.

In one form, it is contemplated that the wire used to form the mesh can be made from stainless steel, cobalt-chrome alloy, titanium, titanium alloy, or nickel-titanium shape memory alloys, among others. It is further contemplated that the metallic wire can be interwoven with non-resorbable polymers such as nylon fibers, carbon fibers and polyethylene fibers, among others, to form a metal-polymer composite weave. Further examples of suitable non-resorbable materials include DACRON and GORE-TEX. In preferred embodiments, the mesh includes one or more reinforcing elements or members attached to the wires. Specific applications for the implants of the present invention include, for example, a prosthetic ligament, a tension band, an interbody fusion or spacer device, or an external fixation device that extends across one or more joints, bone defects or fractures of a bony segment or bone.

It is contemplated that the implants of the present invention can be constructed from one or more layers of mesh material. It is further contemplated that multiple layers of mesh material can be stacked one on top of another and attached by sewing, suturing, rivets, grommets, an adhesive, or other attachment system. It is also contemplated that the mesh layers can be seeded in vitro with bone forming cells, such as osteoblasts, and/or with growth factors. Multiple layers of osteoblast-seeded mesh may be stacked on top of one another and further allowed to or encouraged to proliferate. Due to the attachments formed between cells, a biologic metal-bone composite structure is created in-vitro. Bone growth material or bone material can also be placed between or within the mesh layers.

In one specific form of the present invention, layers of biologic metal-bone composite material can be stacked on top of each other to form a relatively rigid plate for immobilizing fractures or adjacent bone sections. In another form, the mesh material is used to form an annulus repair device. In a further form of the invention, one or more stiff rods may be attached to or placed between the layers of the woven material to act as reinforcing spars. The reinforced implant can be used in lieu of a fixation plate, for example, to wrap around a long bone to immobilize a fracture.

In another form of the present invention, the mesh material can be used to form a hollow implant having application as an interbody fusion device or interbody spacer. It is also contemplated that the mesh material can be seeded in vitro with osteoblasts,

and/or formed with bone growth material or bone material between or within the layers. The hollow implant can act as a bag or container for holding material that allows the implant to resist compressive loads. Some examples of curable materials include those that are flowable above the body temperature, but solidify or otherwise cure in vivo to form a rigid core in the bag. Other examples of curing materials include polyacrylate, polymethacrylate, poly(methyl)methacrylate, calcium sulfate, various forms of calcium phosphate, and liquid silicone. Bone graft, hydrogel, or other non-curable material could be placed in the hollow interior. In a further form, the implant could be formed around a solid body made from bone or metal, for example.

In one embodiment, the hollow implant is in the form of a bag that has a hollow interior, an open end and an opposite closed end. The bag can have reinforcing fibers that extend through the hollow interior across at least the internal diameter of the bag. The bag can be flexible; for example, the bag can be collapsed much like a deflated balloon. The collapsed or smaller bag would facilitate surgical implantation at the targeted treatment site. The bag may be filled with a curing material under sufficient pressure in its liquid state to tension the reinforcing fibers and expand the bag to a desired volume either prior to or more preferably after implantation. Once the material cures, residual tensile stresses left in the reinforcing fibers apply compressive stress to the cured matrix material, thereby modulating the bulk mechanical properties of the structure.

In other embodiments, the mesh material forms a hollow implant that has an injection port through which bone growth material or other curing material can be injected. Once filled with material, the injection port can be closed by sutures, staples, adhesive, caps, and the like. Alternatively, the port can be self-sealing. In one specific application, the hollow implant is an interbody cage or spacer is insertable into an intervertebral disc space.

The mesh material of the present invention may be modified in a number of ways, including electrochemical surface modifications, coating applications and thermal treatments. For example, the mesh material can be anodized, can be thermally hardened, can have interwoven collagen material, can have collagen molecules immobilized to its surface, can be coated/impregnated with an elastomer, adhesive or a

therapeutic agent, or can have alternating strands of metal wires and demineralized bone matrix or collagen. The alternate weave pattern may be used to adsorb or otherwise attach bone morphogenetic proteins, antibiotic agents or other therapeutic or beneficial molecules.

These and other aspects, forms, embodiments, features and advantages of the present invention will be apparent from the following description of the illustrated embodiments.

BRIEF DESCRIPTION OF THE FIGURES

Figs. 1(a), 1(b), 1(c), and 1(d) illustrate various weave patterns for mesh layers used to construct implants according to various embodiments of the present invention.

Fig. 2(a), 2(b), and 2(c) illustrate various steps in forming mesh layers and base members used to construct implants according one embodiment of the present invention.

Fig. 3 is a plan view of a ligament implant according to one embodiment of the present invention.

Fig. 4 is a plan view of a bone plate implant according to another embodiment of the present invention.

Figs. 5(a) and 5(b) are an elevational view and a top plan view, respectively, of an annulus repair and ligament implant according to a further embodiment of the present invention.

Fig. 6 is an elevational view of the annulus repair and ligament implant of Figs. 5(a) and 5(b) attached to an annulus and the adjacent vertebrae.

Fig. 7 is a plan view of a stabilization implant according to another embodiment of the present invention.

Fig. 8 is an elevational view of the implant of Fig. 7 wrapped around a bone defect.

Fig. 9 is a perspective view of one embodiment of a hollow implant according to another form of the present invention.

Fig. 10 is a sectional view taken through line 10-10 of Fig. 9.

Fig. 11 is a perspective view of another embodiment hollow implant according to the present invention.

5 Fig. 12 is a perspective view of yet another embodiment hollow implant according to the present invention.

Fig. 13 is a perspective view of a further embodiment hollow implant according to the present invention.

10 DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the illustrated embodiments and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any such alterations and
15 further modifications of the invention, and any such further applications of the principles of the invention as illustrated herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention relates to orthopedic implants made from metal material forming a mesh from which an implant can be fabricated. In a preferred form, the metal
20 material includes metal wire or fiber of suitable tensile strength and which is not subject to substantial creep deformation or in vitro degradation. Preferably, the wire is of such size and/or material that the implant is flexible yet inelastic. It is contemplated that the metal mesh can be formed by weaving or knitting the wires into the desired pattern, or by attaching the wires to one another in the desired pattern by welding, thermal bonding,
25 electrochemical adhesion, adhesive, or other attachment process.

As shown in Fig. 1(a), a number of small diameter wires 26, 27 can be woven, knit, or attached in any number of patterns to form a metal mesh member 25 from which an implant according to the present invention can be made. In Fig. 1(a) the weave pattern of wires 26, 27 is substantially orthogonal in the x-y directions. Wires 26, 27
30 form mesh member 25 with a rectangular grid-like pattern that has similar tensile properties in both the x and y directions. It is contemplated that the implant made from

mesh member 25 can be oriented such that the wires in either the x-direction or the y-direction extend along the central axis A of the bone member(s) to which the implant is to be attached.

As shown in Fig. 1(b), the wires 26', 27' may also be non-orthogonal relative to one another and/or non-orthogonal relative to the central axis A of the bone member(s) to which the implant is to be attached. This allows the implant made from mesh member 25' to have force-resistance properties that are varied along differing axes in order to enhance the implant's resistance to various forces. Thus, it is contemplated that the angle α and the angle β can each be any angle selected from the range between 0° and 180°. Furthermore, it is possible to utilize more than two wire directions for forming the weave. It is further contemplated that a mesh 28 could be formed that has wires extending along multiple weave axes x, y, a, and z as shown in Fig. 1 (c). In this form the mesh member resembles a three dimensional structure having devised dimensions in width, height and depth along the X, Y, and Z axis respectively. Fig. 1(d) depicts a weave that utilizes wires 26'', 27'' which are curled, rather than straight to form mesh 25''.

Figs. 2(a) through 2(c) illustrate various steps in the method of forming a base member 200 using mesh members 25, 25', 25'' and 28. As shown in Fig. 2(a), a mesh member 27 having one of the weave patterns discussed above is provided. In one preferred form, the mesh member 27 includes cells 110 such as osteoblasts that are injected or seeded onto the mesh in vitro. In order to encourage cell proliferation, the seeded mesh member 29 can be suspended in a medium receptive to cell growth and concurrently subjected to tensile loading as shown in Fig. 2(b). Tensile forces that are applied to mesh member 29 in the x and y direction illustrated as F_x and F_y , respectively, have a range of load and duration of application that creates an environment conducive to osteoblast proliferation, maturation, cell adhesion, and calcification. As shown in Fig. 2(c), two mesh members 29 are then placed one on top of another in order to form base member 100 from which an implant can be fabricated. These multiple layers can be secured to one another by grommets, sewing, knitting, interweaving, suture, applying an adhesive, riveting, thermal bonding, or other technique. Preferably, the multiple layers are secured to one another by encouraging the seeded cells to

proliferate and attach to one another. The desired shape for the implant is cut out and/or pressed or molded into a desired configuration from the base member 100 either before or preferably after seeding the layers with living cells.

5 It is contemplated that multiple layers of orthogonal mesh members 25, non-orthogonal mesh members 25', or combinations of orthogonal/non-orthogonal mesh members 25, 25', 25'' and 28 can be stacked one upon another. The properties of each layer and the properties between the various layers can be varied in order to modulate the properties of the implant in various directions and in various locations. The implant can be a laminated construct having differing plies or layers. This allows the properties of
10 base member 100 to be varied in specific regions for any number of purposes, such as to provide extra reinforcement in highly loaded regions, allow for a specific stress-strain response pattern, or to provide predetermined failure locations on the implant.

The present invention contemplates that various materials may be used for the metal wire used in the mesh members 25, 25', 25'' and 28. Examples of such materials
15 include stainless steels, cobalt chrome alloys, titanium, titanium alloys, and nickel titanium. It is further contemplated that the metal wires forming mesh members 25, 25', 25'' and 28 can be interwoven with non-metallic materials such as nylon fibers, carbon fibers, fibers made from collagen strands, or polyethylene fibers, for example. In a preferred embodiment the selected materials provide a radiopaque implant.

20 The wire used to form mesh members 25, 25', 25'' and 28 can be modified through a number of processes, such as electrochemical surface modifications, coating applications, thermal treatments and so forth. For example, mesh members 25, 25', 25'' and 28 can be made from a titanium wire and subsequently anodized. Another surface modification that is contemplated is to provide collagen immobilized to the surface of
25 mesh members 25, 25', 25'' and 28. Other treatments contemplate that mesh members 25, 25', 25'' and 28 can be thermally treated before and/or after weaving. Mesh members 25, 25', 25'' and 28 can also be coated or impregnated with an elastomer such as silicone or polyurethane or a bone cement.

30 In addition to in vitro seeding of osteoblasts, other treatments for the mesh members 25, 25', 25'' and 28 are contemplated that also provide an implant that allows for bone ingrowth and regeneration of bony tissue. For example, in one embodiment the

mesh members 25, 25', 25'' and 28 are provided with alternating strands of metal wire and demineralized bone matrix. In another embodiment, mesh members 25, 25', 25'' and 28 are smeared or coated with an osteoinductive bone paste, such as OSTEOFIL. In another embodiment, mesh members 25, 25', 25'' and 28 have alternating strands of metal wires and collagen, and the mesh members 25, 25', 25'' and 28 are subsequently soaked in a pharmacological agent such as recombinant human bone morphogenic protein, antibiotic agents, or other similar material. Still other embodiments contemplate no treatment is provided on mesh members 25, 25', 25'' and 28.

Several layers of mesh members 25, 25', 25'' and 28 can be stacked on top of another to form base member 100, which is then cut or molded into the desired shape for use as a bone plate, ligament, annulus repair device, intervertebral cage or interbody spacer, or fracture immobilization device. The desired geometry of the implant can be cut from base member 100 using any number of cutting processes appropriate to the combination of materials and geometries used in the implant design.

Referring now to Fig. 3, one embodiment of an implant made from the mesh material of the present invention is illustrated. Implant 20 has a mesh portion 22 having a generally rectangular or square shape. In the illustrated embodiment, the mesh portion is bounded by a reinforcing band 31. Mesh portion 22 has a number of holes 24 therethrough through which fasteners may be placed to secure implant 20 to bone or other tissue of a patient. Grommets or other reinforcing material may be placed around holes 24 to reinforce the holes and provide secure gripping between the fasteners and mesh portion 22. The fasteners can for the implants of the present invention include screws, staples, sutures, tacks and the like, which may or may not be formed of metallic materials. Furthermore bone adhesives such as calcium phosphate, polymethacrylate and the like can be used with the implants of the present invention. In one specific application, implant 20 can be used to replace the resected portion of the anterior longitudinal ligament removed during insertion of one or more interbody fusion devices into an intervertebral disc space from an anterior approach. Implant 20 can be secured to the vertebral bodies on each side of the subject disc space. It is further contemplated that the width of implant 20 could be reduced and a single hole 24 provided at each end of implant 20. Such a reduced width implant 20 could have application to replace other

ligament structures associated with the spinal column or other ligaments in the body. The bone or tissue growth material formed with the mesh portion promotes growth of a replacement ligament and incorporation of implant 20 into the body tissue.

Referring now to Fig. 4, another embodiment implant made from the mesh material of the present invention is illustrated. Implant 90 is provided in the form of a bone plate having a mesh portion 92. Mesh portion 92 has holes 94a, 94b formed therethrough to accommodate screws or other bone engaging fasteners at the enlarged ends 96a, 96b, respectively of the implant 90. In the illustrated embodiment, the middle portion of implant 90 has a reduced width mid-portion 98 to reduce intrusion of implant 90 into the surrounding tissue and vasculature. Implant 90 could have application as a bone plate that extends across a bone fracture and is secured to the adjacent bony sections. Implant 90 could also have application as an anterior, or antero-lateral, or lateral spinal column plate that extends across a disc space and is secured to the adjacent vertebral bodies. Tissue growth material formed with the mesh portion promotes bone growth and fusion and incorporation of implant 90 into the body tissue.

Referring now to Figs. 5(a) and 5(b), a further embodiment implant made from the mesh material of the present invention is illustrated. Implant 30 has application as a prosthetic ligament or a tension band and annulus repair device. Implant 30 has mesh portion 32 with holes 34a, 34b formed in each of the longitudinally extending sections 33a, 33b, respectively. Implant 30 further has laterally extending sections 36a and 36b. One or more reinforcing elements such as rods or spars 38a and 38b can be embedded in or attached to the exterior of mesh portion 32. In the embodiment of Figs. 5(a) and 5(b), spars 38a, 38b extend horizontally between the laterally extending portions 36a, 36b although the spars may be oriented in a number of different directions. Spars 38a, 38b act to reinforce and provide additional stiffness to mesh portion 32. As shown in Fig. 5(b), mesh portion 32 is curved along a radius R in order to conform to the original shape of the disc space annulus and the adjacent vertebral bodies. It is further contemplated that spars 38a and 38b could be stiff metal or plastic rods and/or could be bendable to allow implant 30 to be custom shaped to the annulus and vertebral bodies and to maintain mesh portion 32 in the desired curvature.

In preferred embodiments, spars 38a, 38b are provided to exhibit greater resistance to deformation than that exhibited or observed for a fiber or a finite number of bundled fibers preferably a greater resistance to deformation than a bundle exceeding 10 fibers, still yet more preferably exceeding a bundle of 15 fibers. The individuals spars 38a, 38b can be formed of the same material as the fibers or a different material. If the spars 38a, 38b are formed of the same or similar material as the fibers, the spars 28a, 38b can be thicker and/or heated treated to increase the material strength. Alternatively, the spars can be formed of a different, harder material than the fibers. In one form, the spar exhibits greater tensile strength than the fibers. The spars can induce substantial inelasticity into the implant. The spars can be formed of a shape memory polymeric material, or metal or metal alloy similar to those forming the fibers or the spar can be formed of a shape memory metallic alloy such as NITINOL®.

The spar(s) can be connected or attached to the fibers by a wide variety of methods and materials. Typically the spar(s) will be attached to two or more fibers using the same or similar methods and materials that interconnect the fibers. Although it should be understood that in selected implants the methods/materials used to interconnect the plurality of fibers need not be the same methods/materials used to connect the spar(s) to the fibers.

As shown in Fig. 6, bone engaging fasteners 35a and 35b attach longitudinally extending portions 33a, 33b of implant 30 to vertebra V1 and vertebra V2, respectively. Annulus engaging fasteners 39a, 39b, such as sutures or staples, can be used to attach laterally extending portions 36a, 36b to the annulus surrounding disc space D. It is contemplated that implant 30 can be used in any number of orthopedic applications, such as repair of anterior longitudinal ligaments following anterior intervertebral disc surgery, anterior longitudinal ligament restoration, or to repair the annulus following microdiscectomy surgery or implant insertion in the disc space D. Tissue growth material formed with the mesh portion promotes tissue growth and repair of the annulus.

Referring now to Fig. 7, yet a further embodiment implant made from the mesh material of the present invention is illustrated. Implant 40 has a generally rectangular mesh portion 42 with a number of spars 44a, 44b, 44c, 44d, 44e, and 44f secured thereto as discussed above with respect to implant 30. Implant 40 has one specific application

for repair of a fracture F in bone B as shown in Fig. 8. Implant 40 can be provided to form an annulus. For example, implant 40 can be wrapped around bone B such that spars 44 extend along the axis A of the bone B and across the fracture F. Implant 40 can be secured to bone B by placing one or more surgical fixation devices 46, such as a SONGER cable, around the implant 40. It is also contemplated that wires, screws, sutures, anchors, staples or other fastening devices can be used to secure implant 40 to bone B to immobilize fracture F. Alternatively, one or more spars 44a-44f can be provided to conform the implant about the bone B, particularly a bone defect. The spars 44a-44f can be pre-formed. Alternatively, spars 44a-44f can be formed of a deformable or shape memory material adapted to conform to or bear against bone B. Tissue growth material formed with the mesh portion promotes tissue growth and incorporation into the body tissue.

The mesh material of the present invention also has application with bags or other devices capable of holding various curing materials that are to be inserted internally to repair a fracture or to span a joint, such as between vertebrae. For example, in Fig. 9 there is illustrated a tubular structure 50 that includes a mesh portion 52 having a generally cylindrical shape. Mesh portion 52 has an end opening 54 through which curable material could be placed and an opposite closed end 58. As shown in Fig. 10, multiple single wire strands 56 extend across and interconnect the walls of mesh portion 52. Curing material, such as polymethylmethacrylate, calcium sulfate, calcium phosphate, or liquid silicone can be placed or injected through end opening 54 and into the hollow interior of implant 50. The curing material can be either in its initial form or in its cured form either an amorphous material or a crystalline or substantially crystalline material. The material as it cures can develop a pressure internally in implant 50, and internal wires 56 become stressed radially outwardly. The spars, if included, can further support the wire stands and/or resist over deformation induced by the curing material. When the injected material hardens, the residual stress formed in wires 56 (and optionally in the spars) applies a compressive force to the injected, cured material.

The mechanical properties of the injected material can be altered to meet design parameters by varying the properties of the wire reinforcement. Examples of parameters that can be varied include the diameter of the wire, the number of wires, direction of the

wires, and injection pressure for the curing material. The surface finish of the wire can also be treated to alter the surface interactive properties of the wire in relation to the injected material. For example, the wire can be provided with a coating or a thermal treatment in order to alter specific properties. The tissue growth/bone growth material used with implant 50 promotes bone growth and fusion and incorporation of implant 50. Also the external surface of the implant fibers treated with a bone cement to secure the implant to a selected bone or tissue structure.

Referring now to Fig. 11, another embodiment hollow implant formed with mesh material of the present invention is illustrated. Implant 60 has a mesh wall portion 62 that defines a hollow interior. Implant 60 further has a first end 64 and an opposite second end 66. An injection port 68 is provided at second end 66. Curable material is injectable through port 68 and into the hollow interior of implant 60 using various injection devices. For example, a syringe, catheter or the like can be used. In selected embodiments a commercially available injection device, sold under the trade name PARALLAX or similar device can be used with the present invention. Once implant 60 is filled with material and the material is cured, then implant 60 is substantially incompressible and capable of supporting compressive loads. Implant 60 can be provided with a detachable cap that is attachable to port 68 after material is injected into implant 60. Alternatively implant 60 can include one or more self-sealing ports that allow influx of a curable material but prevent leakage of the curing/cured material even under the extreme compressive loads excerpted by the spinal column. Implant 60 has application as an interbody spinal fusion device that can be inserted singly or in side-by-side relation with a second implant 60 into a spinal disc space in order to support the spinal column and facilitate fusion between the adjacent vertebral bodies. It is further contemplated that implant 60 could be inserted into the interior of a bone for fracture repair. The tissue/bone growth material used with implant 60 promotes bone growth along with fusion and incorporation of implant 60.

As shown in Fig. 12, another embodiment of a hollow implant made with the mesh material of the present invention is shown. Implant 70 has a mesh wall portion 72 defining a hollow interior and an injection port 74. Implant 70 has upper and lower surfaces that have a shape that allows these surfaces to occupy a substantial area of the

vertebral endplates. Implant 70 further has a height between these upper and lower surfaces that allows the normal disc space height to be restored. One or more implants 70 could be inserted into a spinal disc space. The tissue/bone growth material used with implant 70 promotes bone growth along with fusion and incorporation of implant 70.

5 Referring now to Fig. 13, another embodiment hollow implant made with the mesh material of the present invention is illustrated. Implant 80 has mesh wall portion 82 defining an interior cavity into which curable material may be injected through a port 84. Implant 80 has C-shape or other generally annular shape defining a holding area 86. A bone graft can be positioned in holding area 86 before or after implant 80 is filled with
10 material. The tissue/bone growth material used with implant 80 promotes bone growth along with fusion and incorporation of implant 80 along with the bone graft.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the illustrated embodiments have been shown
15 and described, and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. An orthopedic implant comprising:
a bone fixating prosthesis comprising an interconnecting network of
5 metallic fibers, and
one or more reinforcing elements secured to said network of metallic
fibers, wherein said implant is adapted for promoting fusion between adjacent bone
structures.
- 10 2. The implant of claim 1 comprising at least one of an osteogenic
material or a pharmaceutical agent.
3. The implant of claim 1 comprising fibers formed of one or more
of: stainless steel, cobalt-chrome alloy, titanium, titanium alloy, or nickel-titanium shape
15 memory alloys.
4. The implant of claim 1 wherein the network of fibers is
substantially nonelastic.
- 20 5. The implant of claim 1 wherein the network of fibers comprises a
three dimensional array of fibers.
6. The implant of claim 1 wherein the network of fibers comprises a
deformable sheet or fabric-like material.
- 25 7. The implant of claim 6 wherein at least a portion of the network of
fibers is deformable to conform to a selected bone structure.
8. The implant of claim 1 comprising a second network of fibers
30 formed of a material selected from the group consisting of: biocompatible polymeric
materials, nylon fibers, carbon fibers, glass fibers, collagen fibers, ceramic fibers,

polyethylene fibers, poly(ethylene terephthalate), polyglycolides, polylactides, and combinations thereof.

5 9. The implant of claim 8 wherein the second network of fibers is biodegradable.

10 10. The implant of claim 1 comprising reinforcing elements formed of a material selected from the group of: stainless steel, cobalt-chrome alloy, titanium, titanium alloy, or nickel-titanium shape memory alloys, biocompatible polymeric materials, nylon fibers, carbon fibers, glass fibers, collagen fibers, ceramic fibers, polyethylene fibers, poly(ethylene terephthalate), polyglycolides, polylactides, and combinations thereof.

15 11. The implant of claim 1 wherein said interconnecting network of fibers comprises a first set of fibers interwoven or bonded to a second set of fibers.

 12. The implant of claim 1 adapted to secure to at least two adjacent vertebral bodies to promote spinal fixation.

20 13. The implant of claim 1 adapted to be inserted into a prepared disc space to promote spinal fusion.

 14. The implant of claim 1 wherein at least a portion of the interconnecting network of fibers is impregnated with an osteogenic material.

25 15. The implant of claim 1 comprising a first interconnecting network of fibers overlaid with a second interconnecting network of fibers.

30 16. The implant of claim 15 wherein the first interconnecting network of fibers comprises a three dimensional array of fibers.

17. The implant of claim 15 wherein the implant is deformable to conform to a selected bone structure.

18. The implant of claim 15 wherein the first and second network of fibers are secured together using a securing element selected from the group consisting of: an adhesive, a curable polymeric material, a suture, a staple, and combinations thereof.

19. The implant of claim 15 wherein the first and second network of fibers are secured together to provide a barrier sufficiently porous to permit interdiffusion of an osteogenic material therethrough.

20. The implant of claim 1 comprising a second set of fibers formed of a biocompatible polymeric material.

21. The implant of claim 1 wherein the reinforcing element is formed of a shape memory polymeric or metallic alloy material.

22. The implant of claim 1 wherein the reinforcing element is adapted to conform to a preselected bone structure.

23. The implant of claim 1 adapted to interconnect proximal bone structures as a prosthetic ligament, a tension band or an external fixation device.

24. A bone plate comprising:
an interconnecting network of metallic fibers providing a substantially nonelastic bone support;
an osteogenic material impregnated on said fibers, and
a bone fastener.

25. The bone plate of claim 24 comprising fibers formed of a shape memory metallic alloy.

26. The bone plate of claim 24 comprising fibers formed of one or more of: stainless steel, cobalt-chrome alloy, titanium, titanium alloy, or nickel-titanium shape memory alloys.

27. The bone plate of claim 24 wherein the network of metallic fibers comprises a three dimensional array of fibers.

28. The bone plate of claim 24 wherein the interconnecting network of metallic fibers is deformable to conform to a selected bone structure.

29. The bone plate of claim 24 wherein the bone fastener is a bone cement.

30. The bone plate of claim 24 wherein the bone fastener comprises at least one of: a bone screw, a suture, or a staple.

31. The bone plate of claim 24 comprising one or more reinforcing elements formed of a material selected from the group of: stainless steel, cobalt-chrome alloy, titanium, titanium alloy, or nickel-titanium shape memory alloys, biocompatible polymeric materials, nylon fibers, carbon fibers, glass fibers, collagen fibers, ceramic fibers, polyethylene fibers, poly(ethylene terephthalate), polyglycolides, polylactides, and combinations thereof.

32. An orthopedic implant for promoting bone fusion, said implant comprising:

a body including a wall portion formed of an interconnecting network of metallic fibers, said body defining an internal cavity; and
at least one reinforcing element connected to said fibers.

33. The implant of claim 32 comprising an osteogenic material.

34. The implant of claim 32 comprising fibers formed of one or more
of: stainless steel, cobalt-chrome alloy, titanium, titanium alloy, or nickel-titanium shape
memory alloys.

35. The implant of claim 32 wherein the network of metallic fibers is
substantially nonelastic.

36. The implant of claim 32 wherein the network of fibers comprises a
three dimensional array of fibers.

37. The implant of claim 32 comprising an opening through said wall
portion into said internal cavity.

38. The implant of claim 32 comprising a core material disposed in
the internal cavity.

39. The implant of claim 38 wherein the core material comprises an
osteogenic material.

40. The implant of claim 38 wherein the core material is a curable
material.

41. A method of treating a bone defect, said method comprising
implanting an implant according to claim 35 proximal to a bone defect.

42. An orthopedic implant comprising:
a plurality of metallic fibers interconnected together at junctures to form a
network;

two or more elongate members extending across a portion of the network adjacent said junctures, each of said elongate members provided to exhibit a tensile strength greater than a selected metallic fiber of the plurality of metallic fibers;

5 an osteogenic material impregnated in said network, wherein said implant is adapted to induce bone fusion between adjacent bone structures.

43. An orthopedic implant for promoting bone fusion, said implant comprising:

10 a body including a wall portion formed of an interconnecting network of metallic fibers, said body defining an internal cavity and having an opening through the wall portion into the internal cavity; and

15 at least one elongated member extending into said cavity, said elongate member provided to exhibit a tensile strength greater than a selected metallic fiber of the interconnecting network of metallic fibers wherein said implant is adapted to induce bone fusion between adjacent bone structures.

44. An orthopedic implant for connecting adjacent bone structures, said implant comprising:

20 an interconnecting network of metallic fibers each fiber joined to an adjacent fiber at a juncture; said interconnecting network bounded by a reinforcing band;

two or more elongate members extending across a portion of the network adjacent said junctures, each of said elongate members provided to exhibit a tensile strength greater than a selected metallic fiber of the interconnecting network of metallic fibers;

25 an osteogenic material adhered to at least a portion of the implant, said implant adapted to promote bone ingrowth.

45. Method of treating a bone defect, said method comprising:
preparing a site of treatment to accept an orthopedic implant;

implanting proximal to said site an orthopedic implant comprising
an interconnecting network of metallic fibers, and one or more reinforcing elements
secured to said network of metallic fibers,
applying an osteogenic material to said implant or to said bone
defect to promote bone fusion.

46. The method of claim 45 wherein said implant is a bone plate.

47. The method of claim 45 wherein said implant is a bone spacer.

48. The method of claim 45 wherein said implant comprises a body
defining a cavity.

49. The method of claim 45 wherein said applying comprising
applying the osteogenic material to the implant prior to implantation.

50. The method of claim 45 wherein said applying comprising
applying the osteogenic material to the implant after implantation.

FIG. 1(a)

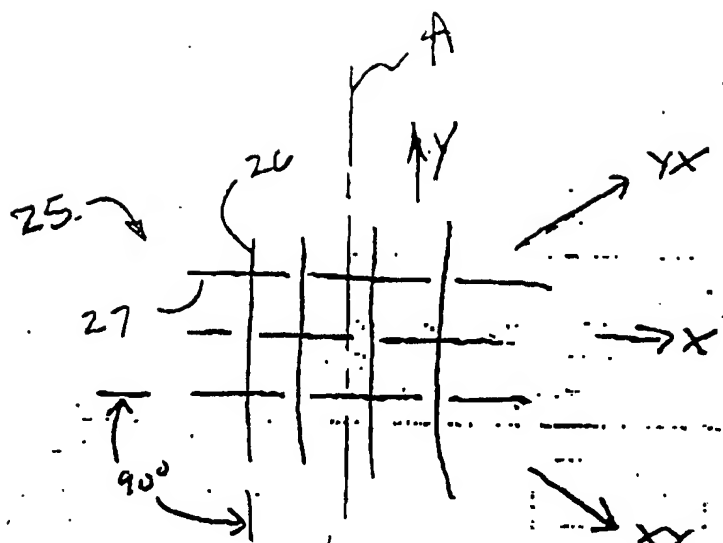


FIG. 1(b)

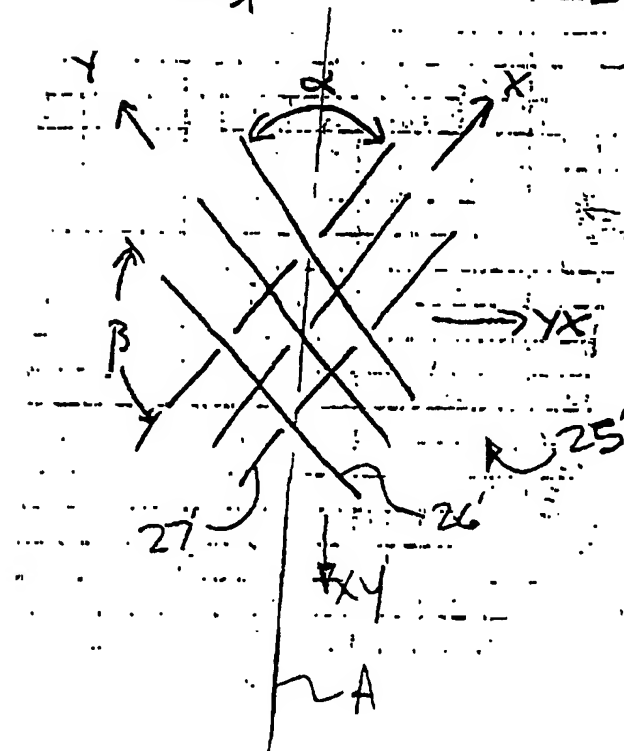


FIG 1(c)

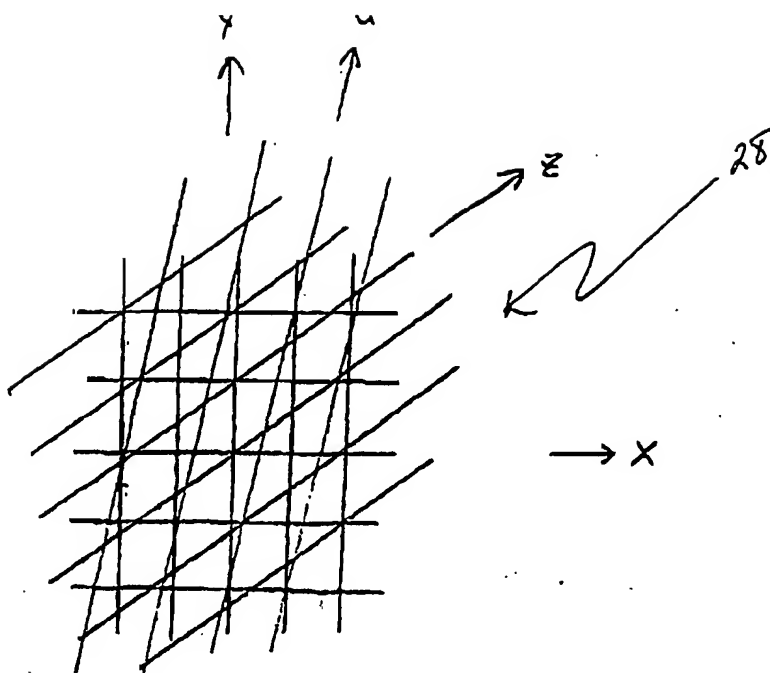


FIG 1(d)

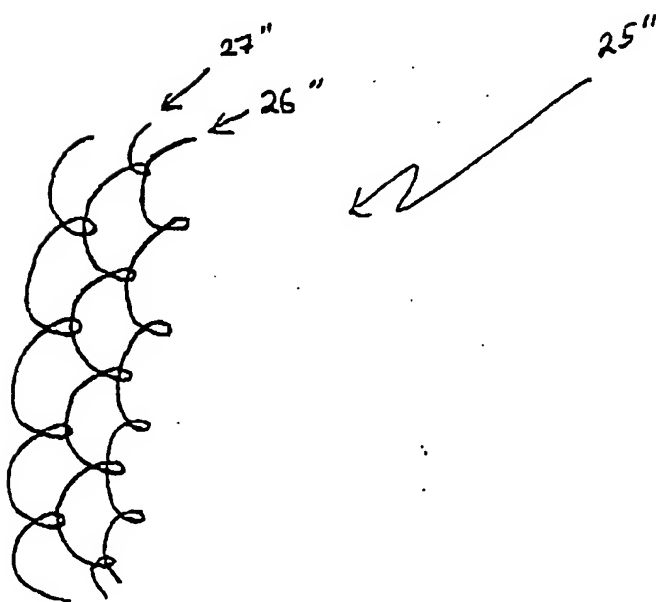


FIG. 2(a)

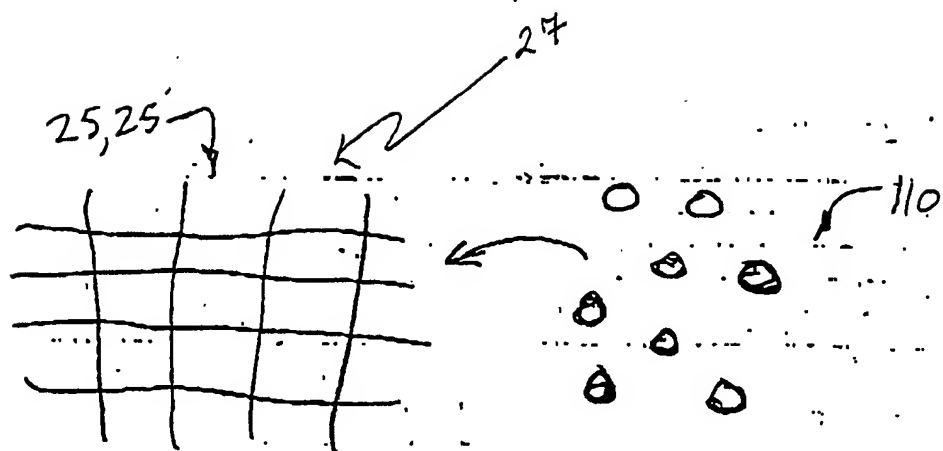


FIG. 2(b)

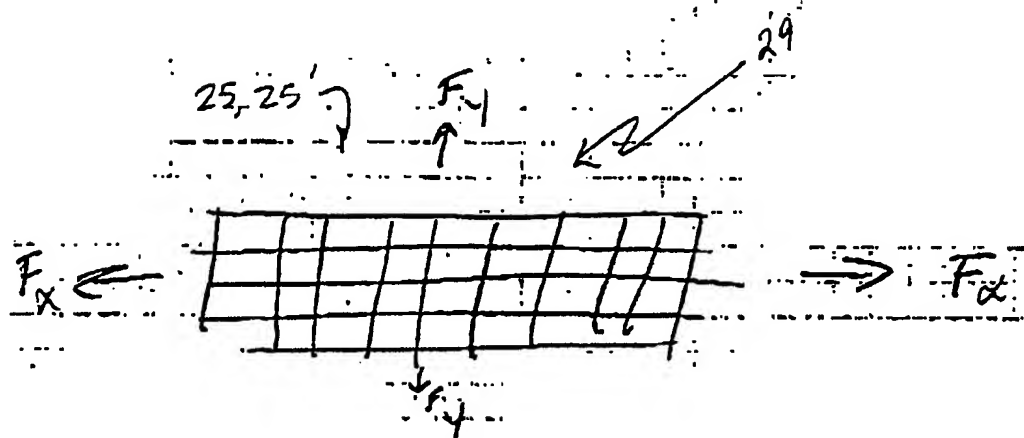


FIG. 2(c)

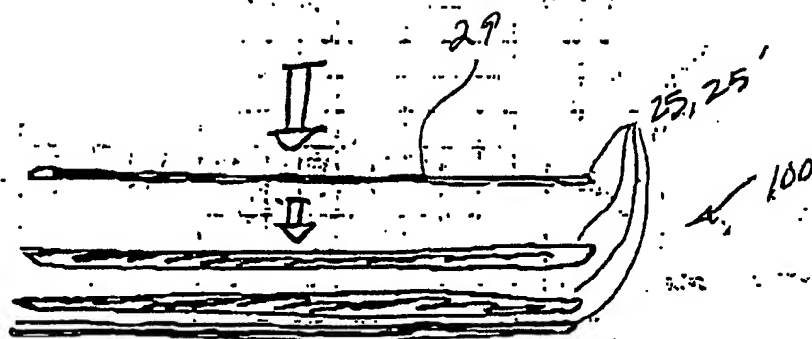


FIG. 3

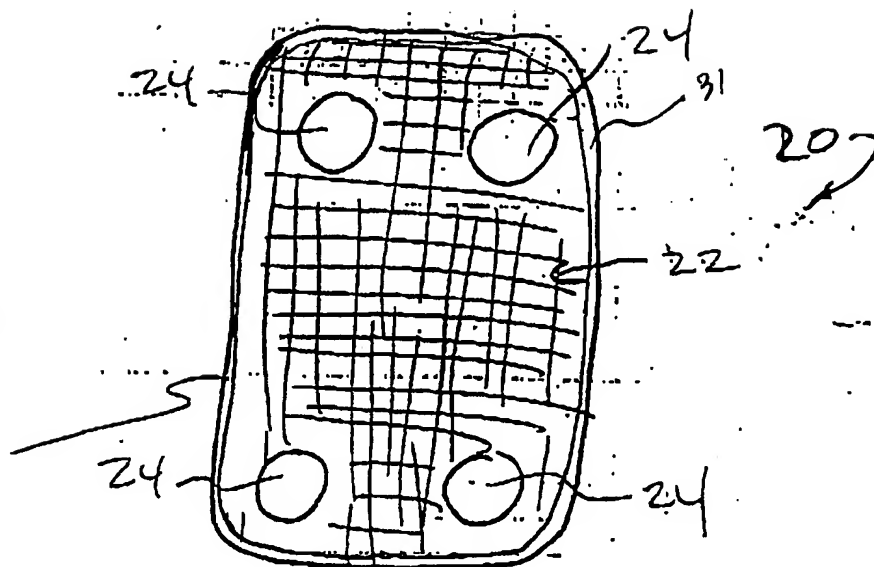
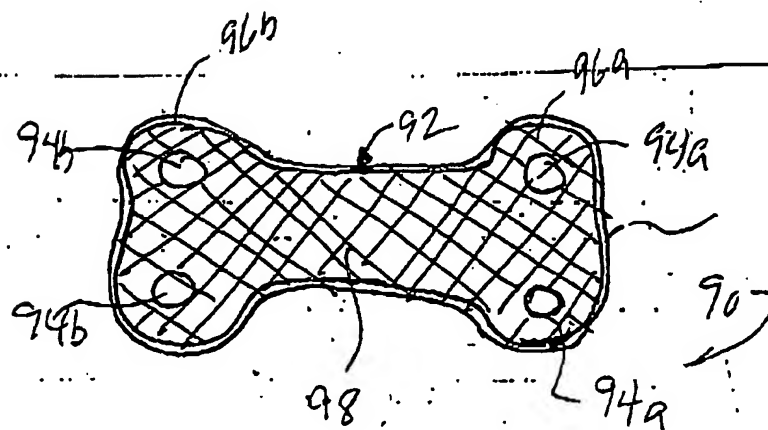


FIG. 4



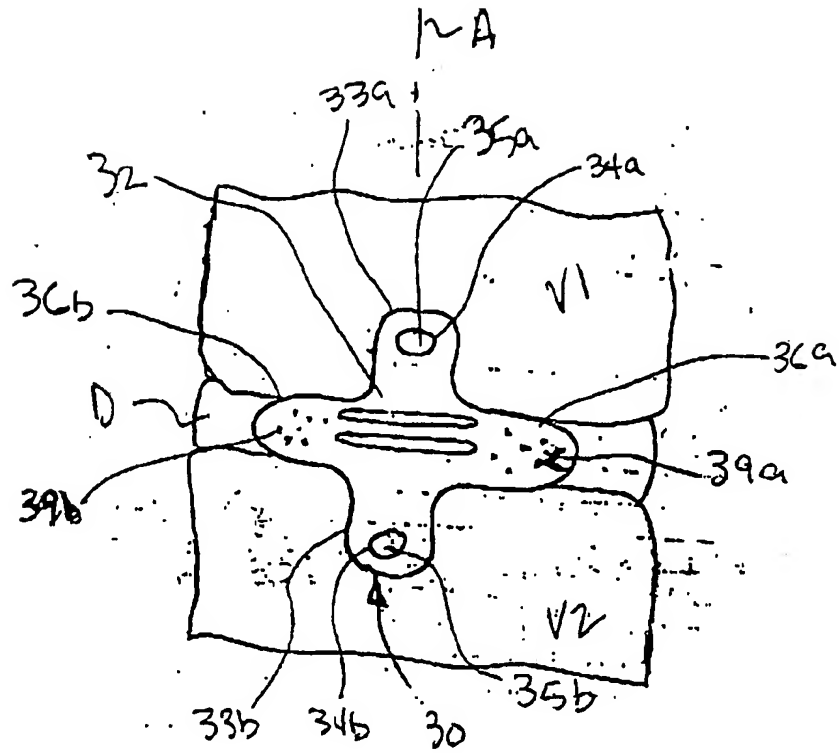


FIG. 6

FIG. 5(a)

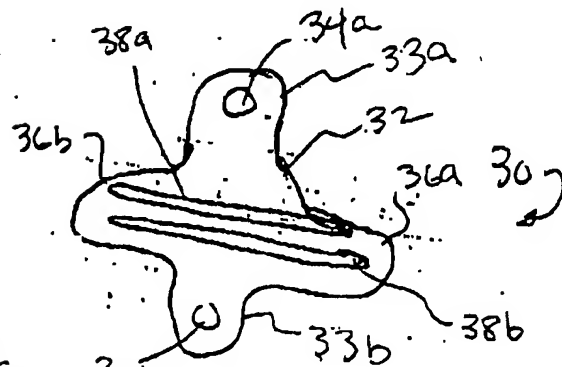
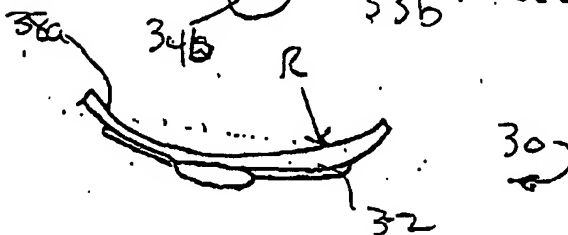


FIG. 5(b)



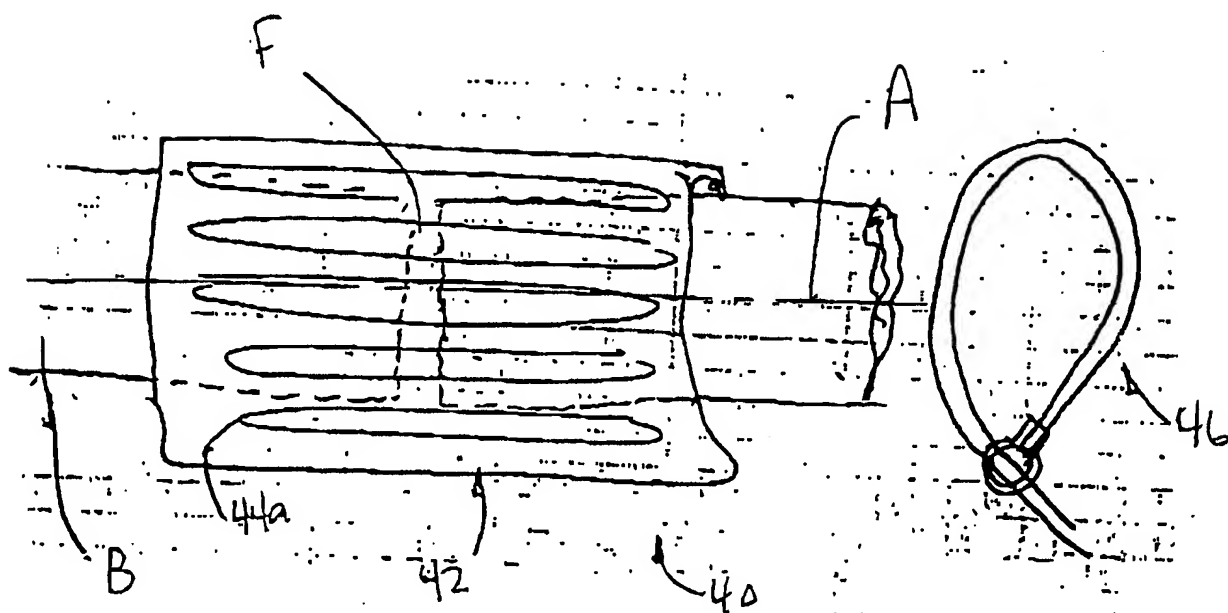


FIG. 8

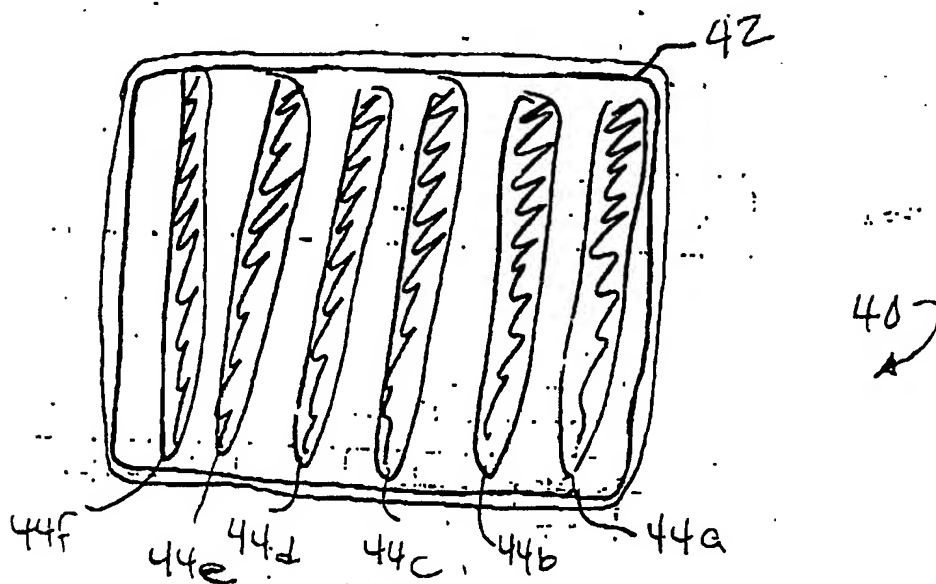


FIG. 7

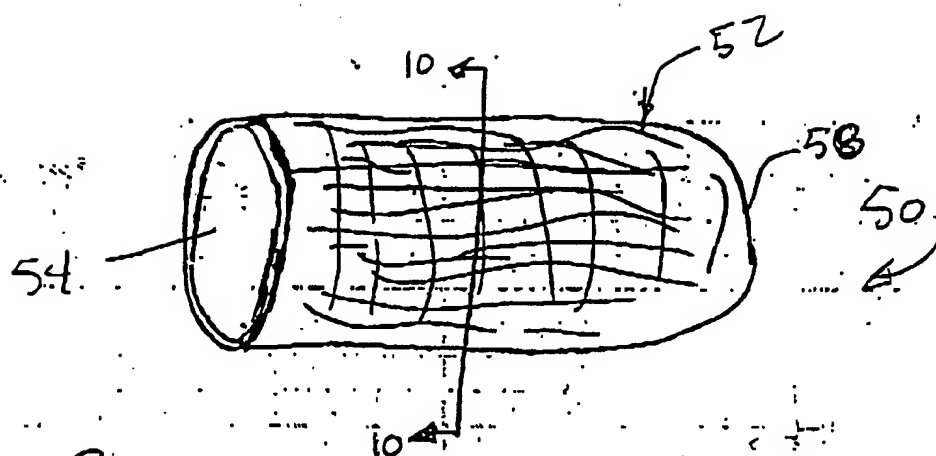


FIG. 9

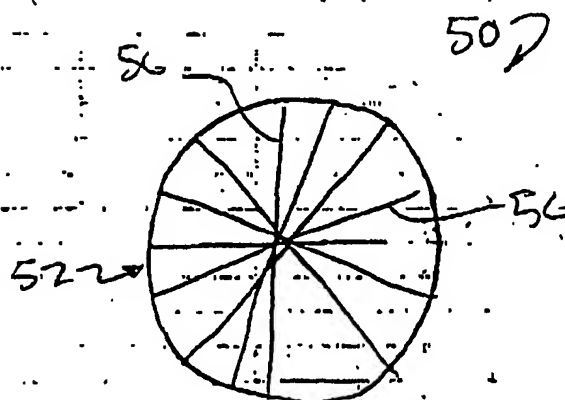
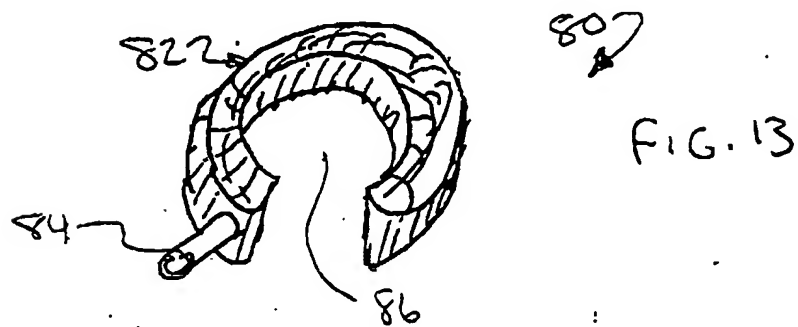
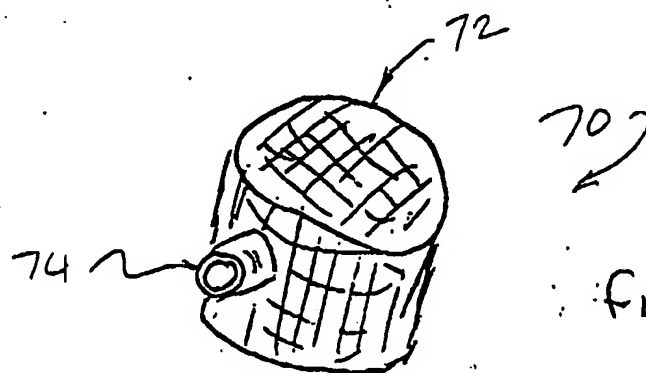
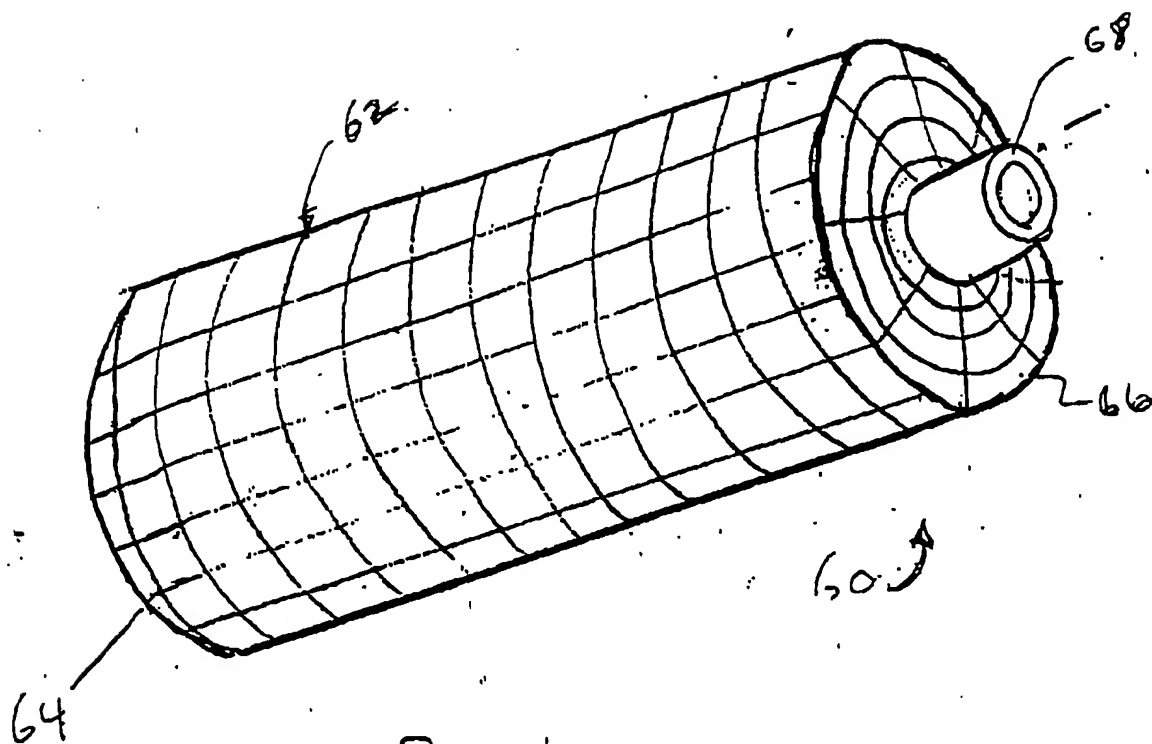


FIG. 10



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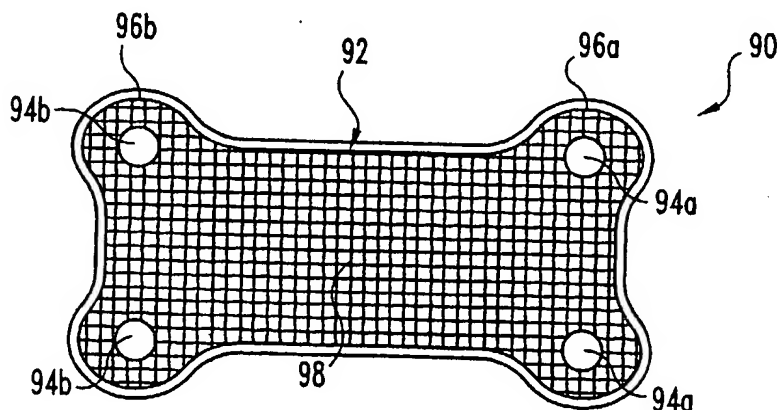
Previous Correction:

see PCT Gazette No. 01/2003 of 3 January 2003, Section II

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AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
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For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: WOVEN ORTHOPEDIC IMPLANTS



(57) Abstract: The present invention relates to orthopedic implants made from a mesh material. The mesh material can be treated in order to promote bone growth, to provide antibiotics, or to provide other beneficial treatment. Specific applications for the implants include, for example, a prosthetic ligament, a tension band, an interbody device, or a fixation device that extends across one or more joints or fractures.

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INTERNATIONAL SEARCH REPORT

International Application No

PC1/US 02/06211

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F2/44 A61F2/28 A61B17/80 A61B17/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/012081 A (FREI RETO ; HEHLI MARKUS (CH); SYNTHES AG (CH); DUDA GEORG (DE); SY) 22 February 2001 (2001-02-22) page 3, paragraph 4 - page 4, paragraph 1 page 9, paragraph 2 - page 10, paragraph 1 figures 5,6	1,5
Y	----- -/--	2-4,6-8, 11, 14-20, 32,35-37

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the International filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"Z" document member of the same patent family

Date of the actual completion of the International search

24 September 2003

Date of mailing of the International search report

13. 01. 04

Name and mailing address of the ISA

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Storer, J

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/06211

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>US 5 380 328 A (MORGAN FRANK H) 10 January 1995 (1995-01-10)</p> <p>column 1, line 27 - line 38 column 4, line 41 - line 44 column 6, line 30 - line 58 column 7, line 28 - line 54 column 8, line 28 - line 37 figures 6-8</p>	<p>3,4,6-8, 11, 15-20, 32,35-37</p>
Y	<p>-----</p> <p>US 6 077 076 A (COMFORT CHRISTOPHER J) 20 June 2000 (2000-06-20) column 4, line 6 - line 15 column 4, line 52 - column 5, line 11 column 5, line 66 - column 6, line 2 column 6, line 42 - line 45 figure 5</p>	<p>2,14</p>
P,X	<p>-----</p> <p>EP 1 088 533 A (SULZER ORTHOPEDICS LTD) 4 April 2001 (2001-04-04)</p> <p>paragraph [0008] - paragraph [0013] paragraph [0017] figures</p> <p>-----</p>	<p>1-3,5, 8-13,16, 20,22, 32-34, 36-39</p>

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/06211

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 41, 45-50
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-23, 32-40, 43

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

Continuation of Box I.1

Claims Nos.: 41,45-50

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-23, 32-40,43

An orthopaedic implant comprising:

- a bone fixating prosthesis comprising an interconnecting network of metallic fibres; and
- one or more reinforcing elements secured to said network of metallic fibres.

2. claims: 24-31, 42, 44

An orthopaedic implant comprising:

- an interconnecting network of metallic fibres;
- a osteogenic material impregnated on said fibres.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/06211

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0112081	A	22-02-2001	DE 29913994 U1 AU 759419 B2 AU 2791400 A CA 2405235 A1 WO 0112081 A1 CN 1368866 T EP 1202675 A1 JP 2003506189 T	21-12-2000 17-04-2003 13-03-2001 22-02-2001 22-02-2001 11-09-2002 08-05-2002 18-02-2003
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EP 1088533	A	04-04-2001	EP 1088533 A1 US 6447543 B1	04-04-2001 10-09-2002